



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. 09/964,065

Applicant: KOVESDI et al.

Filed: September 26, 2001

TC/AU: 1632

Examiner: PRIEBE, Scott D.

Docket No.: 213257

Customer No.: 23460

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that any reference listed thereon is prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that they represent art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that the references are not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or
- ☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

#### Copies of the References

☐ Copies of all of the references listed on the enclosed Form 1449 are enclosed herewith.

☒ Copies of U.S. patents and patent applications that are listed on the accompanying Form 1449 are not enclosed herewith. Copies of other references identified on the accompanying Form 1449 are enclosed herewith.

☐ Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).

☐ A copy of the foreign search report is enclosed herewith.

☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the

details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		STATUS (CHECK ONE)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

#### Statement under § 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

#### Statement under § 1.704(d)

- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

#### Fees

- ☒ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180** under § 1.17(p) is enclosed herewith.

#### Method of Payment of Fees

- ☐ Attached is a check in the amount of \$180.00.
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$180.00. (A duplicate copy of this communication is enclosed for that purpose.)

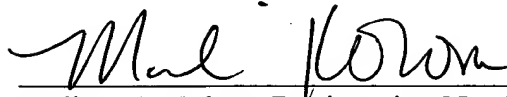
#### Authorization to Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

**Instructions as to Overpayment**

- ☒ Credit Account No. 12-1216.  
☐ Refund.

Respectfully submitted,



Melissa E. Kolom, Registration No. 51,860

**LEYDIG, VOIT & MAYER, LTD.**

Two Prudential Plaza, Suite 4900

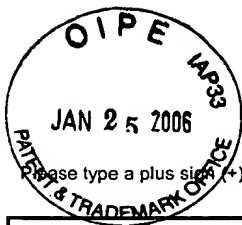
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Date: January 25, 2006



JAN 25 2006

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PTO/SB/08A/B (08-03)  
Approved for use through 07/31/2006. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

<b>Substitute for form 1449A/B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/964,065
				Filing Date	September 26, 2001
				First Named Inventor	KOVESDI, Imre
				Group Art Unit	1636
				Examiner Name	PRIEBE, Scott David
Sheet	1	of	3	Attorney Docket Number	213257

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>1</sup>	Cite No.	U.S. Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Document Number	Kind Code			
	CG	US- 4,497,796		02-05-1985	Salser et al.	
	CH	US- 4,727,028		02-23-1988	Santerre et al.	
	CI	US- 4,740,463		04-26-1988	Weinberg et al.	
	CJ	US- 5,190,931		03-02-1993	Inouye	
	CK	US- 5,208,149		05-04-1993	Inouye	
	CL	US- 5,518,913		05-21-1996	Massie et al.	
	CM	US- 6,040,174		03-21-2000	Imler et al.	
	CN	US- 6,127,175		10-03-2000	Vigne et al.	
	CO	US- 6,133,028		10-17-2000	Imler et al.	

FOREIGN PATENT DOCUMENTS								
Examiner Initials <sup>1</sup>	Cite No.	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear	Check if Translation Provided**
		Office	Number	Kind Code				
	CP	AU	95/28533		03-21-1996	Introgene B.V.		<input type="checkbox"/>
	CQ	CA	2,053,187	A1	04-11-1993	Natl. Res. Council		<input type="checkbox"/>
	CR	WO	94/24297	A	10-27-1994	Rhone-Poulenc Rorer		<input checked="" type="checkbox"/>
	CS	WO	94/26914	A	11-24-1994	Rhone-Poulenc Rorer		<input checked="" type="checkbox"/>
	CT	WO	95/16772	A	06-22-1995	Cornell Res. Found.		<input type="checkbox"/>
	CU	WO	96/13596	A	05-09-1996	Rhone-Poulenc Rorer		<input checked="" type="checkbox"/>
	CV	WO	96/18418	A	06-20-1996	Genetic Therapy, Inc.		<input type="checkbox"/>
	CW	WO	96/22378	A	07-25-1996	Rhone-Poulenc Rorer		<input checked="" type="checkbox"/>

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

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Examiner Signature		Date Considered	
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<sup>1</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



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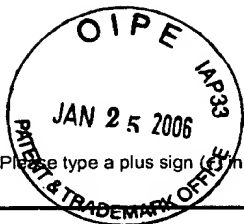
OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
	CX	BROUGH et al., "A gene transfer vector-cell line system for complete functional complementation of adenovirus early regions E1 and E4," <i>J. Virol.</i> , 70 (9), 6497-6501 (1996).	<input type="checkbox"/>
	CY	BRUNET et al., "Concentration dependence of transcriptional transactivation in inducible E1A-containing human cells," <i>Mol. Cell. Biol.</i> , 8 (11), 4799-4807 (November 1988).	<input type="checkbox"/>
	CZ	BYRD et al., "Malignant transformation of human embryo retinoblasts by cloned adenovirus 12 DNA," <i>Nature</i> , 298 (5869), 69-71 (July 1, 1982).	<input type="checkbox"/>
	DA	CRYSTAL et al., "Administration of an adenovirus containing the human <i>CFTR</i> cDNA to the respiratory tract of individuals with cystic fibrosis," <i>Nature Genet.</i> , 8, 42-51 (1994).	<input type="checkbox"/>
	DB	GALLIMORE et al., "Properties of rat cells transformed by DNA plasmids containing adenovirus type 12 E1 DNA or specific fragments of the E1 region: comparison of transforming frequencies," <i>Cancer Res.</i> , 45 (6), 2670-2680 (June 1985).	<input type="checkbox"/>
	DC	GRODZICKER et al., "Expression of unselected adenovirus genes in human-cells co-transformed with the HSV-1-TK gene and adenovirus 2 DNA," <i>Cell</i> , 21 (2), 453-463 (September 1980).	<input type="checkbox"/>
	DD	KETNER et al., "Complementation of adenovirus E4 mutants by transient expression of E4 cDNA and deletion plasmids," <i>Nucl. Acids Res.</i> , 17 (8), 3037-3048 (April 25, 1989).	<input type="checkbox"/>
	DE	KLINMAN, "Introduction to the issues: Viral vectors and potential problems in their use," <i>Developments in Biological Standardization</i> , 76, 299-300 (S. Karger AG, Basel, Switzerland, 1992).	<input type="checkbox"/>

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

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Examiner Signature		Date Considered	
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OTHER - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials <sup>1</sup>	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Check if Translation Provided**
	DF	LEWIS et al., "Viral messenger RNA in six lines of adenovirus-transformed cells," <i>Virology</i> , 115 (2), 345-360 (December 1981).	<input type="checkbox"/>
	DG	ROBERTS et al., "Individual adenovirus type 5 early region 1A gene products elicit distinct alterations of cellular morphology and gene expression," <i>J. Virol.</i> , 56 (2), 404-413 (November 1985).	<input type="checkbox"/>
	DH	WANG et al., "Second-generation adenovirus vectors," <i>Nature Med.</i> , 2 (6), 714-716 (1996).	<input type="checkbox"/>
	DI	YANG et al., "Inactivation of <i>E2a</i> in recombinant adenoviruses improves the prospect for gene therapy in cystic fibrosis," <i>Nature Gen.</i> , 7, 362-369 (1994).	<input type="checkbox"/>
	DJ	ZHOU et al., "Progress towards development of an adenoviral vector with deletions of E1 and E2a," <i>J. Cell. Biochem., Supp.</i> 21A, 434 (1995).	<input type="checkbox"/>
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